



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,446	12/31/2003	Samuel Steinemann	1409-2 RCE/CON	1771

7590 12/28/2007
Daniel A. Scola Jr.
Hoffmann & Baron, LLP
6900 Jericho Turnpike
Syosset,, NY 11791

EXAMINER

MORILLO, JANEL COMBS

ART UNIT	PAPER NUMBER
----------	--------------

1793.

MAIL DATE	DELIVERY MODE
-----------	---------------

12/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/750,446	Applicant(s) STEINEMANN, SAMUEL	
	Examiner Janelle Combs-Morillo	Art Unit 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/445675.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

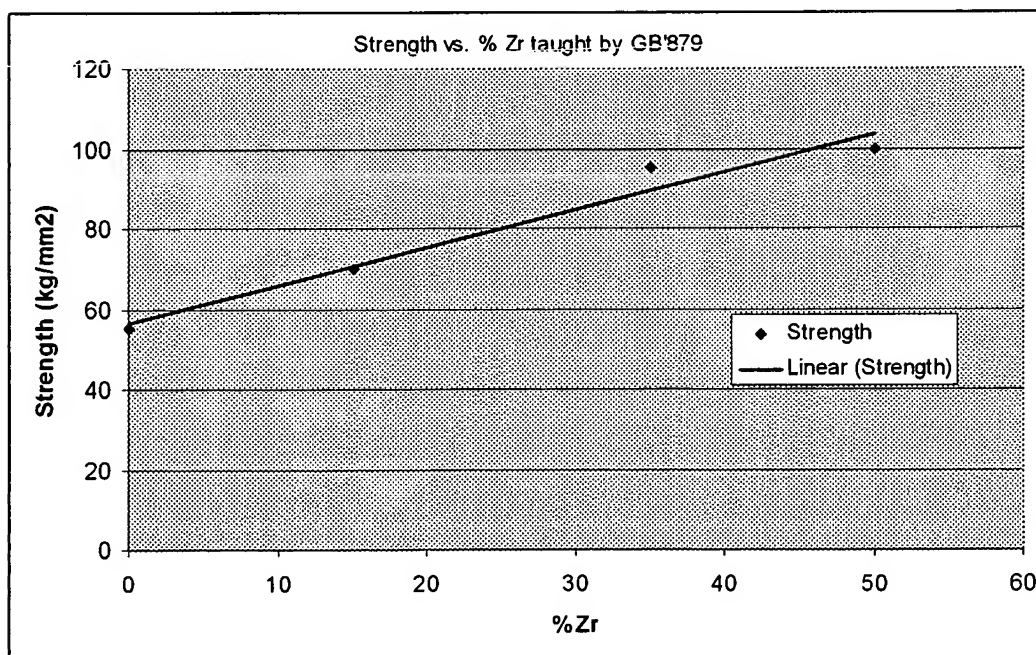
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 11, 14-15, 17-19, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1,305,879 (GB'879).

GB'879 further teaches an example with 15% Zr obtains a moderate strength and high elongation (p 2 of GB'879). Broadly, GB'879 teaches a titanium alloy suitable for medical implants, wherein said alloy preferably consists of 25-75% Zr, (page 2 lines 47-50). GB'879 teaches that up to 2% O₂ is typically present in "technically-pure titanium" and furthermore applicable to the alloys taught by GB'879, wherein said oxygen is present as an impurity or rigidity increasing addition (page 2 lines 75-79), which overlaps the presently claimed range of oxygen. The Ti-Zr alloy taught by GB'879 is a single phase alloy (see Ti-Zr phase diagram).

Overlapping ranges have been held to be a prima facie case of obviousness, see MPEP § 2144.05. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994).

Concerning claim 11, which mentions a TS of ≥ 769 MPa is achieved for a Ti-Zr alloy with 10-19% Zr, though GB'879 is drawn to binary Ti-Zr alloy with high amounts of Zr in order to obtain high strength, GB'879 teaches that the amount of added Zr is directly related to the strength achieved, and therefore is a result effective variable (wherein the expected result is increase in strength and decrease in elongation with increasing amounts of Zr, see Table p 2).



A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). It would have been obvious to one of ordinary skill in the art to select the Zr amount/range and strength combination because GB'879 teaches a direct relationship between Zr and strength achieved, and wherein the instant strength minimum is expected to result from a Ti- Zr alloy within the instant range taught by GB'879 (see Table 2, Ti-15% Zr achieves a strength of 70 kg/mm², Ti-35% Zr achieves strength of 95 kg/mm², and wherein Ti-19% Zr is expected to be in-between said strength values, which is approximately 75 kg/mm². Though 75 kg/mm² does not meet the instant minimum of >769 MPa= 78.4 kg/mm², GB'879 teaches the strength of the alloys hot rolled and annealed alloys in said table can be further increased by about 30 kg/mm² by cold working (p 2 lines 43-46). Therefore, the Ti-Zr alloy taught by GB'879 is held to produce the predictable result of moderate strength and elongation.

Concerning independent claim 11 (and dependent claim 19), GB'879 does not mention making said alloy by the presently claim process steps. However, GB'879 does mention the strength of the alloys can be further increased by about 30 kg/mm² by cold working, and without elongations falling below 15% (p 2 lines 43-46). Further with regard to the instant product by process limitations, it is well settled that a product-by-process claim defines a product, and that when the prior art discloses a product substantially the same as that being claimed, differing only in the manner by which it is made, the burden falls to applicant to show that any process steps associated therewith result in a product materially different from that disclosed in the prior art.

See MPEP 2113, *In re Brown* (173 USPQ 685) and *In re Fessman* (180 USPQ 524) *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Because applicant has not shown that the Ti-Zr alloy product taught by GB'879 is materially different than the presently claimed product by process, it is held that GB'879 has created a prima facie case of obviousness of the presently claimed invention.

Concerning claims 14, 21, 23, as stated above, GB'879 teaches a titanium alloy suitable for medical implants, wherein said alloy consists of 15% Zr balance Ti (see table on page 2), which overlaps the presently claimed alloying ranges.

Concerning claims 15, 17, 18, 22, 23, GB'879 teaches a titanium alloy suitable for medical implants (column 2 lines 80-86), wherein said alloy preferably consists of 25-75% Zr, (page 2 lines 47-50), or (less preferably) lower ranges of Zr -wherein lowered ranges of Zr are expected to exhibit the predictable result of moderate strength properties. GB'879 teaches the corrosion and tissue compatibility of binary Ti-(15-85%)Zr alloys is as good as those of pure metals (see Table, see also p 2 lines 63-65).

4. Claims 11, 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB'879 in view of Chem. Ab. no. 103239 (hereinafter CA'239) and Davidson (US 5,169,597 A).

GB'879 is discussed above.

Concerning amended claims 16 and 20, GB'879 teaches a titanium alloy suitable for medical implants, wherein said alloy preferably consists of 25-75% Zr, (page 2 lines 47-50), or (less preferably) lower ranges of Zr -wherein lowered ranges of Zr are expected to exhibit the predictable result of moderate strength properties. GB'879 also teaches the corrosion and tissue

compatibility of binary Ti-(15-85%)Zr alloys is as good as those of pure metals (see Table, see also p 2 lines 63-65).

Concerning the process steps of independent claims 11, 16, 20, 22, GB'879 teaches that said Ti-Zr alloy is hot worked (such as forging, page 3 lines 6-7), annealed, and optionally cold worked (see page 2 Table and line 44). GB'879 does not mention a) the hot forging temperature range, or b) rapidly cooling after hot forging.

Concerning item a), CA'239 teaches that Ti-Zr alloys can be hot forged in the α as well as the $\alpha+\beta$ regions. Because CA'239 teaches a typical hot forging temperature range, and because CA'239 and GB'879 are both drawn to Zr containing Ti alloys, it would have been obvious to one of ordinary skill in the art to hot forge the Ti-Zr medical implant alloy in the α as well as the $\alpha+\beta$ regions (as taught by CA'239) while performing the process as taught by GB'879 of hot forging, annealing, and optionally cold rolling.

Concerning item b), GB'879 does not mention rapidly cooling after hot forging. However, Davidson teaches that rapid cooling after hot working Ti alloys achieves a finer grain size (column 5 lines 21-25, rather than slow cooling) and provides adequate strength (column 3 lines 66-67). It would have been obvious to one of ordinary skill in the art to rapidly cool after hot working the alloy of GB'879, because Davidson teaches that a finer grain size can be achieved, rendering it more suitable for use as an implant material.

Concerning dependent claims 14, 15, 17-19, 21, 23, see discussion of GB'879 in paragraphs above.

Response to Arguments

5. In the response filed on October 31, 2007 applicant amended claims 16, 20, added new claims 22 and 23, and submitted various arguments traversing the rejections of record.

6. Applicant's argument that the present invention is allowable over the prior art of record because GB'879 teaches against the instant invention because GB'879 prefers Ti-Zr alloys with higher amounts of Zr in order to optimize strength, or that the prior art does not mention the combination of tensile strength and elongation at break, has not been found persuasive. As stated above, though GB'879 is drawn to binary Ti-Zr alloy with high amounts of Zr in order to obtain high strength, GB'879 teaches that the amount of added Zr is directly related to the strength achieved, and therefore is a result effective variable (wherein the expected result is increase in strength and decrease in elongation with increasing amounts of Zr, see Table p 2). Changes in concentration or temperature will generally not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical, i.e. they produce a new and unexpected result. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382. A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Because GB'879 teaches examples with increasing levels of Zr (15% Zr, 35% Zr) increase in strength but decrease in ductility, it would have been obvious to one of ordinary skill

in the art to select the desired range of Zr based on said result effective variable of combination of strength and elongation (see also graph and discussion above).

7. Applicant's argument that the present invention is allowable over the prior art of record because GB'879 discloses only an alloy with a Zr content of between 25-75% can be used as surgical or dental implants has not been found persuasive. As stated above, GB'879 teaches a titanium alloy suitable for medical implants (column 2 lines 80-86), wherein said alloy preferably consists of 25-75% Zr, (page 2 lines 47-50), or (less preferably) lower ranges of Zr - wherein lowered ranges of Zr are expected to exhibit the predictable result of moderate strength properties. GB'879 teaches the corrosion and tissue compatibility of binary Ti-(15-85%)Zr alloys is as good as those of pure metals (see Table, see also p 2 lines 63-65).

8. Applicant's argument that the present invention is allowable over the prior art of record because the Ti15Zr alloy of GB'879 exhibits an inferior strength of 70 kg/mm², which is lower than the presently claimed minimum of 78.4 kg/mm² has not been found persuasive. GB'879 teaches the strength of the alloys hot rolled and annealed alloys in said table can be further increased by about 30 kg/mm² by cold working (p 2 lines 43-46). Therefore, the Ti-Zr alloy taught by GB'879 further processed by cold working which GB'879 teaches increases the strength by about 30 kg/mm², is held to produce the predictable result of moderate strength and elongation, and meets the presently claimed strength minimum.

9. When the Examiner has established a *prima facie* obviousness, the burden then shifts to the applicant to rebut. *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (en banc). Rebuttal may take the form of "a comparison of test data showing that the claimed compositions possess unexpectedly improved properties... that the prior art does not have, that

the prior art is so deficient that there is no motivation to make what might otherwise appear to be obvious changes, or any other argument.. that is pertinent.” Id. at 692-93; USPQ2d 1901.

Applicant has not clearly shown specific unexpected results with respect to the prior art of record or criticality of the instant claimed range (wherein said results must be fully commensurate in scope with the instantly claimed ranges, etc. see MPEP 716.02 d).


Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janelle Combs-Morillo whose telephone number is (571) 272-1240. The examiner can normally be reached on 8:30 am- 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jcm
December 20, 2007



ROY KING
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700